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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,079	05/09/2001	Steven G. Reed	210121.426C11	5270

32111 7590 08/08/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/853,079

Applicant(s)

REED ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-2, 9-12, 14, 16, 17-34, 36 is/are pending in the application.
- 4a) Of the above claim(s) 1, 9-11, 14, 17 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 12, 16, 18 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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***Response to Amendment***

1. The amendment filed on 2/24/03 has been entered into the record. Claims 3-8, 13, 15, and 35 have been canceled. Claims 2, 12, 14, 16, 18 and 36 have been amended. Claims 1-2, 9 - 12, 14, 16, 17- 34, 36 are pending in the application. Claims 2, 12, 16, 18 and 36 are under examination as an elected invention. Claims 1, 9-11, 14, 17, 19-34 are withdrawn from consideration as a non-elected invention, said election made in paper # 8.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Rejections Withdrawn***

3. In view of amendment to claims 2, 16, 18 and 36 the rejection under 35 U.S.C. 112, first paragraph is withdrawn.
4. In view of amendment to claim 36, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.
5. In view of amendment to claim 18 and cancelation of the claims 3-6, 8, the rejection under 35 U.S.C. 102(b) as being anticipated by Tetzlaff et al 1990 Molecular and Biochemical Parasitology 40:183-192 is withdrawn.

***Rejections Maintained***

6. The rejection of claims 2, 12, 16, 18 and 36 under 35 U.S.C. 102(b) as being anticipated by Lodes et al (EPO 834567, published in 4/8/1998) is maintained as set forth in the previous Office action.

Claims are directed to an isolated polypeptide, fusion protein, composition and a kit comprising the SEQ.ID.NO: 195 and antigenic epitopes.

Lodes et al disclose an isolated polypeptide SEQ.ID.NO: 53 which contains an isolated polypeptide comprising the SEQ.ID.NO: 195 (100% sequence alignment with SEQ.ID.NO: 53

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from position 218-243), fusion proteins, composition and kit comprising the said (claims and pages 101-102 of patent) polypeptide.

Applicants' arguments filed on 2/24/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that Lodes et al does not disclose an isolated polypeptide that is identical to the structure and to the function of the polypeptide, SEQ.ID.NO: 195. Further, applicant states that Lodes et al disclose the B. microti antigen of SEQ.ID.NO: 53 but does not teach a peptide that is identical to the sequence BMNI-17-4. Therefore, Lodes et al does not disclose BMNI-17-4 peptide, fusion protein, composition and kit of the same.

It is the position of the examiner that the sequence alignment shows that the polypeptide SEQ.ID.NO: 53 disclosed by Lodes et al matches with the claimed SEQ.ID.NO: 195.

Applicant's use of the open-ended term "comprising " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed polypeptide comprising SEQ.ID.NO: 53. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art product and the claimed product are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipates the claimed invention.

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Further, the limitations " BMNI-17-4" and function of the polypeptide are not set forth in the claims. Applicant is arguing about the limitations which are not set forth in the claims. Therefore, the disclosed prior art polypeptide reads on the claimed invention.

***New Objections Based on Amendment***

7. Claims 16, 18 and 36 are objected because the claims recite claim 14, which is not an elected invention.

***Status of Claims***

8. Claims 2, 12, 16, 18 and 36 are rejected.

***Conclusion***

9. This application contains claims 1, 9-11, 14, 17, 19-34 drawn to an invention nonelected with traverse in Paper No. 8 A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

8/4/03

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600